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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124842

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

April 28, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ronald A. Pullen, Vice President
Advanced Home Oxygen and Medical Supplies, Incorporated
42 Hudson Street, Suite A-211
Annapolis, Maryland 21401

Dear Mr. Pullen:

The Food and Drug Administration (FDA) conducted an inspection of your Annapolis, Maryland facility from March 30 to April 7, 1998, and determined that your firm manufactures Oxygen, U.S.P., which is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from Current Good Manufacturing Practice (GMP) Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations, which cause your Oxygen, U.S.P to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, include the following:

1. Failure to adequately test each batch of Oxygen, U.S.P. for conformance to final specifications for the drug product prior to release. Your firm does not calibrate or document the calibration of the oxygen analyzer according to the manufacturer's directions.

2. Failure to adequately calibrate the oxygen analyzer in accordance with the manufacturer's instruction manual. Your firm fails to use a high-purity nitrogen standard to "zero" the analyzer.

3. Failure to assure that each person engaged in the transfilling of compressed medical oxygen, and/or witnessing deliveries of bulk liquid oxygen from suppliers, has the education, training, or experience to enable that person to perform their assigned functions. Your firm failed to establish an adequate training program addressing both on-the-job and GMP training.

4. Failure to calibrate the pressure gauges, vacuum gauges, liquid oxygen scale, and thermometers used during transfilling of Oxygen, U.S.P..

5. Failure to establish adequate written procedures for the production and process controls, designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess, including procedures covering calibration of the oxygen analyzer and pressure gauges, the training of your employees, pre-fill, fill and post-fill operations, and labeling control.

6. Failure to establish written procedures designed to assure that correct labels and labeling are used, including examination of packaging and labeling materials for suitability and correctness prior to packaging operations.

7. Failure to perform adequate pre-fill, fill, and post-fill operations on each high-pressure cylinder filled.

8. Failure to establish batch production records for each batch of Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, and holding of the batch was accomplished at the time of performance. Batch production records lacked the required pre-fill, fill, and post-fill operations performed on each cylinder filled and were not verified for accuracy and completeness by a second individual.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Wiley T. Williamson, III. Mr. Williamson can be reached at (410) 962-4366, extension 136.

Sincerely,

ELAINE KNOWLES COLE
District Director

Enclosure

cc: VA State Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717

Mr. Dennis Carrol
Associate Regional Administrator
HFCA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)